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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,509	12/07/2001	Marie-Claude Gingras		8559

7590 11/06/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
11/06/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
MARIE-CLAUDE GINGRAS and JUDITH F. MARGOLIN

Appeal 2007-3749
Application 10/021,509
Technology Center 1600

Decided: November 5, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellants have requested rehearing of the decision entered March 31, 2008 (hereinafter "Decision"). The Decision affirmed rejections of claims 1, 3, 5, 11, 15, 16, and 40-42 under 35 U.S.C. § 112, first paragraph, as lacking enablement, and under 35 U.S.C. § 102(e) as anticipated. The request for rehearing is denied.

DISCUSSION

Enablement

In our Decision affirming the enablement rejection of the claims, we agreed with Appellants that the Specification was enabling for modulating an immune response *in vivo* by administering a composition comprising a soluble peptide with at least a portion of amino acids 1 to 136 of SEQ ID NO:2, but agreed with the Examiner that it would have required undue experimentation to make and use polyepeptide mimetics of SEQ ID NO:2 in order to modulate an immune response *in vivo*. The rejection was affirmed on that basis (Decision 13).

Appellants contend that we misapprehended the term "peptide mimetics" (Req. 9) when we found a difference in scope between "polypeptides with at least a portion of amino acids 1 to 136 of SEQ ID NO:2" and "a polypeptide mimetic thereof" (Claim 1).

Appellants argue that

> Specification paragraph 75 is clear that peptide mimetics are the same as peptides or functional equivalents and polypeptides. In other words, peptide mimetics or peptidomimetics are simply a synonymous of peptide functional equivalents. In that regard the Specifications paragraph 75 reads ". . . the present inventors also contemplate that structurally similar compounds may be formulated to mimic the key portions of peptide or polypeptides of the present invention. Such compounds, which may be termed peptidomimetics, may be used in the same manner as the peptides of the invention and, hence, also are functional equivalents."

(Req. Reh'g 9-10.)

Appellants argue "the term 'mimic' means structurally similar or having the same biological active structure or sequence" (Req. Reh'g 10), and ask "[h]ow can a peptide mimetic[ ] be structurally similar and not be the same as a peptide with a portion of amino acids 1-136 of SEQ ID:2?" (*id.*). Appellants argue "[a]s long as the formulated peptides bear at least a portion of the Key portion of Sequence ID NO:2 in their structure and display the claimed immunomodulating biological activity, they are subjected to the Claims" (Req. Reh'g 12).

Appellants' arguments are not persuasive. We did not misapprehend a difference in scope between a peptide containing a portion of a defined sequence (SEQ ID NO:2) and a polypeptide mimetic. The Specification does not support Appellants' assertion that the polypeptide mimetics recited in the claims must have at least a portion of the "Key" portion of SEQ ID NO:2. According to the Specification, "[t]he underlying rationale behind the use of peptide mimetics is that is that the peptide backbone of proteins exists chiefly to orient amino acid side chains in such a way as to facilitate molecular interactions . . . similar to the natural molecule" (Spec. ¶ 76), thus "[c]ertain mimetics . . . mimic elements of protein secondary and tertiary structure" (*id.*). That is, mimetics may have a different primary structure (i.e., amino acid sequence) than the natural molecule, yet still approximate the shape and charge distribution of the natural molecule. Thus, the genus of "polypeptides with at least a portion of amino acids 1 to 136 of SEQ ID NO:2" is narrower than the genus of "polypeptide mimetics thereof" recited in claim 1. Moreover, claim 1, on its face, distinguishes between the two in

reciting "soluble polypeptides with at least a portion of amino acids 1 to 136 of SEQ ID NO:2 *or* a polypeptide mimetic thereof" (emphasis added).

We concluded that the Specification is not enabling for the broad scope of the claims for reasons discussed on pages 11-14 of the Decision, and we decline to modify our decision affirming the rejection of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Anticipation by Ruben

With respect to our affirmance of the Examiner's rejection of the claims as anticipated by Ruben, Appellants contend a "misapprehension . . . in [the] Decision . . . where it is being stated that Reuben's SEQ ID NO:478 is identical to [Appellants'] SEQ ID NO:2" (Req. Reh'g 14). Appellants are correct in that Ruben's SEQ ID NO:478 represents the amino acid sequence of membrane-bound TREM-1, while Appellants' SEQ ID NO:2 represents the soluble TREM-1 splice variant, TREM-1sv, which "contains only 150 amino acids because of a deletion from amino acid 136 to 200 that is coding for the transmembrane portion of TREM-1" (Req. Reh'g 14).

Nevertheless, claim 1, in pertinent part, is directed to "modulating an immune response" by administering "a composition of soluble polypeptides with at least a portion of amino acids 1 to 136 of SEQ ID NO:2" (claim 1). Amino acids 1 to 136 of SEQ ID NO:2 are included in Ruben's SEQ ID NO:478, therefore, we decline to modify our disposition of the claims on the basis of this misapprehension.

Appellants further contend that "there is misapprehension of the teaching of their invention by reducing it to the teaching of [Ruben]" (Req Reh'g 15). Specifically, Appellants argue that Ruben "teaches a molecule

with the natural binding activity of Ig that can bind a large variety of antigens that may modulate the immune response but . . . does not teach the macrophage TREM-1 ligand complex-receptor" (Req. Reh'g 16), while "Appellants claim and present validation of biological activity for the loop domain or portion of it being a key sequence of SEQ ID NO:2 and for its usage in the treatment of conditions that can benefit from capturing that specific TREM-1 receptor binding ligand with TREM-1sv or derived peptides before it reaches the myeloid expressed TREM-1 activating receptor" (*id.*).

Appellants' argument is not persuasive. Claim 1, in pertinent part, is broadly directed to modulating an immune response by administering a composition of soluble polypeptides with at least a portion of amino acids 1 to 136 of SEQ ID NO:2, to an animal in need thereof. As we noted on page 15 of the Decision, Ruben teaches administering polypeptides comprising portions of SEQ ID:478 - at least some of which correspond exactly to portions of Appellants' SEQ ID NO:2 - to animals to treat (i.e., modulate) a variety of immune system disorders. We recognize that Appellants propose a specific mechanism for that modulation not identified by Ruben. However, "when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005). *See also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) ("Newly

discovered results of known processes directed to the same purpose are not patentable because such results are inherent.").

Accordingly, we decline to modify our decision affirming the rejection of the claims under 35 U.S.C. § 102(e) as anticipated by Ruben.

SUMMARY

We modify the previous Decision to the extent that we acknowledge that Ruben's SEQ ID NO:478 differs from Appellants' SEQ ID NO:2 in that Ruben's sequence includes the transmembrane domain of TREM-1, while Appellants' sequence represents the splice variant of TREM-1 (TREM-1sv) in which the transmembrane sequence is deleted. However, we decline to modify our original disposition of the claims under 35 U.S.C. §§ 102(e) and 112, first paragraph, for the reasons discussed above, and in the Decision.

REHEARING DENIED

LP

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